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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,096	09/18/2003	Brian R. MacDonald	PRD-2110-USANP	1638
27777 7570 08/12/2009 PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			EXAMINER	
			BUNNER, BRIDGET E	
			ART UNIT	PAPER NUMBER
THE PROPERTY			1647	
			MAIL DATE	DELIVERY MODE
			08/12/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

### Application No. Applicant(s) 10/667.096 MACDONALD ET AL. Office Action Summary Examiner Art Unit Bridget E. Bunner 1647 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 23 June 2009. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 2-12.15-19 and 26-34 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) 2-8,15-19 and 26-33 is/are allowed. 6) Claim(s) 9-12 is/are rejected. 7) Claim(s) 34 is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on 18 September 2003 and 01 February 2007 is/are; a) ☐ accepted or b) ☐ objected to by the Examiner Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)

Paper No(s)/Mail Date \_

Notice of Draftsherson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO/SB/08)

Paper No(s)/Mail Date.

5) Notice of Informal Patent Application

6) Other: PTO-90C: Revised Notice to Comply.



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### DETAILED ACTION

The finality of the Office action mailed 07 April 2009 is hereby withdrawn in view of the new issues set forth below.

# Status of Application, Amendments and/or Claims

The amendment of 23 June 2009 has been entered in full. Claims 2, 9, 10, 11 and 12 are amended. Claims 1, 13, 14, 20-25 are cancelled.

Claims 2-12, 15-19, 26-34 are under consideration in the instant application.

### Withdrawn Objections and/or Rejections

- The rejection of claims 2-12, 15-19, and 26-34 under 35 U.S.C. § 112, second paragraph as set forth at page 2 of the previous Office Action (07 April 2009) is withdrawn in view of the amended claims (23 June 2009).
- 2. The objection under 35 U.S.C. § 132 for introduction of new matter into the disclosure as set forth at pages 3-5 of the previous Office Action (07 April 2009) is withdrawn in view of Applicant's persuasive arguments (23 June 2009). Specifically, at page 7 of the Response, Applicant states that the claims of provisional application 60/498,740 (incorporated by reference) clearly recite the "LAARX<sub>10</sub>" sequence.
- 3. The rejection of claims 2-12, 15-19, and 26-34 under 35 U.S.C. § 112, first paragraph (new matter) as set forth at pages 5-7 of the previous Office Action (07 April 2009) is withdrawn in view of Applicant's persuasive arguments (23 June 2009). Specifically, at page 7 of the Response, Applicant states that the claims of provisional application 60/498,740 (incorporated by reference) clearly recite the "LAARX<sub>10</sub>" sequence.

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### Sequence Compliance

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). Specifically, the TPO mimetic sequence disclosed in claims 2 and 9-12 is not accompanied by the required reference to the relevant sequence identifier. Additionally, the specification discloses the same TPO mimetic sequence at two locations on page 7 that are not accompanied by the required reference to the relevant sequence identifier. This application fails to comply with the requirements of 37 CFR 1.821 through 1.825. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825). Please also see attached PTO-90C Communication and Revised Notice to Comply.

### Priority

5. The amendment to the specification filed 08 January 2009 attempted to claim priority to provisional Application No. 60/498,740, filed August 28, 2003. However, this amendment is an untimely claim for priority. The reference to a prior-filed provisional application must be submitted during the pendency of the later-filed application. Specifically, if the later-filed application is an application filed under 35 U.S.C. 111(a), this reference must be submitted within the later of four months from the actual filing date of the later-filed application or sixteen months from the filing date of the prior-filed provisional application. These time periods are not extendable. The failure to timely submit the reference is considered a waiver of any benefit under 35 U.S.C. 119(e) to such prior-filed provisional application. See MPEP § 201.11 and 37 CFR 1.78. Applicant is encouraged to amend the first line of the specification to remove reference to provisional Application No. 60/498,740.

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# Claim Objections

6. Claim 34 is objected to because of the following informalities:

6a. In claim 34, line 2, the term "thereapy" is misspelled and should be amended to recite "therapy".

Appropriate correction is required.

# Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- Claims 9-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 8. Claims 9-12 are indefinite because the claims do not have a step that clearly relates back to the preamble. For example, in claim 9, there is no step indicating a reducing a time to engraftment of stem cells. (Please note that this issue could be overcome by amending line 7 of claims 9-12. For example, claim 9, line 7 could be amended to recite, "transplanting the one or more harvested stem cells in to the subject to thereby reduce a time of engraftment of stem cells".)

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#### Conclusion

The art made of record and not relied upon is considered pertinent to applicant's disclosure:

Kuter et al. Blood 100(10): 3457-3469, 2002 (review of the activities of TPO)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BEB Art Unit 1647 05 August 2009